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10/602,129	06/24/2003	Scot R. Shepard	2001.689USD1	1596
67706 7590 10/06/2008 ORGANON USA, INC. c/o Schering-Plough Corporation 2000 Galloping Hill Road Mail Stop: K-6-1, 1990 Kenilworth, NJ 07033				
EXAMINER				
MCMILLIAN, KARA RENTA				
ART UNIT		PAPER NUMBER		
1617				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/602,129

Applicant(s)

SHEPARD, SCOT R.

Examiner

KARA R. MCMILLIAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-14 and 16-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-14 and 16-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Detailed Action

Claims 10-14 and 16-29 are pending.

Priority

This application is a divisional of application number 09/855634 now U.S. Patent No. 6,635,679.

Response to Arguments/Amendments

The applicant's amendments received on December 2, 2005 amending claims 10, 12-14 and 16 and adding new claims 17-29 has been entered. Claims 10-14 and 16-29 are currently pending.

The rejection under 35 USC § 102 (b) of claim 10-16 in the office action sent out on June 3, 2005 is hereby withdrawn due to the amending of claims 10-16 in the reply filed on December 2, 2005.

Applicant's arguments to the objection of claim 14 in the reply filed on December 2, 2005 has been fully considered and found persuasive. As such, the objection to claim 14 in the office action mailed on June 3, 2005 is hereby withdrawn.

As a result of Applicant's amendments to claims 10-14 and 16 and the addition of new claims 17-29 the following new rejections are as set forth below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Birnie et al. (Antimicrobial Evaluation of N-Alkyl Betaines and N-Alkyl-N,N-dimethylamine Oxides with Variations in Chain Length, Sept. 2000, Antimicrobial Agents and Chemotherapy, Vol. 44, No. 9, pp. 2514-2517).

Claims 18-20 of the instant application claim a method of inactivating a viral or microbial agent in a biological source material, comprising contacting the biological source material with a solution consisting essentially of an effective amount of an amine oxide, wherein the amine oxide is selected from the group consisting of: dimethyldecylamineoxide, dimethylundecylamineoxide, dimethyldidecylamineoxide and dimethyltridecylamineoxide. Claims 21-24 of the instant application claim the method of claims 18-20 wherein the solution consists essentially of a detergent and an amine oxide.

The examiner respectfully points out that for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are,

"consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355. If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In *re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of" is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of language.").

Birnie et al. teach, in the abstract of page 2514, that alkyl betaines and alkyl dimethylamine oxides have been shown to have pronounced antimicrobial activity when used individually or in combination. Birnie et al. teach on page 2514, that the composition C31G (equivalent to an equimolar mixture of N-alkyl betaine and N-alkyl-N,N-dimethyl amine oxide) exhibited pronounced activity against bacteria, sperm, yeasts, fungi and enveloped viruses. In Table 3 on page 2515, Birnie et al. show the activity of N-alkyl-N,N-dimethylamine oxides against the bacteria *S. aureus* and *E. coli* as a function of alkyl chain length. Table 3 clearly indicates that N-alkyl-N,N-

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dimethylamine oxides have antimicrobial activity, including the amine oxides currently claimed. Specifically claims 18-24 of the instant application claim dimethyldecylaminoxide which is equivalent to C₁₀ amine oxide and dimethyldidecylamineoxide which is equivalent to C₁₂ amine oxide (see Table 3 page 2515).

Birnie et al. also teach effective concentrations of N-alkyl-N, N-dimethylamine oxide within the range claimed in the instant application (see Table 3 on page 2515). Thus claims 18-20 are anticipated by Birnie et al. In addition, Birnie et al. also teaches the combination of amine oxides with betaine detergents. Birnie et al. also teach effective concentrations of betaine detergents within the range claimed in claim 24 of the instant application (see Table 2 on page 2515). Thus claims 21-24 are also anticipated by Birnie et al.

Claim Rejections - 35 USC § 103

Claims 10-14 and 16-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fonsny et al. U.S. Patent No. 5,911,915 in view of Rasmussen et al. Publication No. US 2002/0022649 A1.

Claims 10-14 and 16-17 of the instant application claim a method of inactivating a viral or microbial agent in a biological source material, comprising contacting the biological source material with a solution comprising an effective amount of an amine, wherein the amine is selected from the group consisting of: dimethyldecylamine, dimethyltridecylamine, dimethylundecylamine, dimethyldidecylamine,

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dimethyltetradecylamine, and dimethylhexadecylamine. Claims 18-20 of the instant application claim a method of inactivating a viral or microbial agent in a biological source material, comprising contacting the biological source material with a solution consisting essentially of an effective amount of an amine oxide, wherein the amine oxide is selected from the group consisting of: dimethyldecylamineoxide, dimethylundecylamineoxide, dimethyldidecylamineoxide and dimethyltridecylamineoxide. Claims 21-24 of the instant application claim the method of claims 18-20 wherein the solution consists essentially of a detergent and an amine oxide. Claims 25-29 of the instant application also claim the method of claims 18-20 wherein the solution consists essentially of a polyol and an amine oxide.

Fonsny et al. disclose a stable, clear, multipurpose, hard surface cleaning composition especially effective in disinfecting the surface being cleaned (see column 2 lines 19-21). The composition disclosed by Fonsny et al. comprises among other ingredients, 0.1% to 20% of a nonionic surfactant and/or an ethoxylated glycerol type compound, 0.1% to 20% of at least one disinfecting agent such as a cationic surfactant, and 0.1% to 20% of an amphoteric surfactant (see column 2 lines 47-58). Fonsny et al. further discloses that the compositions contain preferably 0.25% to 8% of a disinfectant agent selected from C₈-C₁₆ alkyl amines, and that amine oxides can be optionally used at a concentration of 0 to 10%, more preferably 0.1% to 8% (see column 8 lines 45-67). Fonsny et al. further discloses in column 9 lines 1-13 the formula of suitable amine oxides which can be any one of the amine oxides claimed in claims 18-29 of the instant application.

Fonsny et al. further discloses in column 9 lines 14-59 that the composition can also optionally contain 0-10%, more preferably 0.1 to 8% of an amphoteric surfactant such as betaine detergents.

Fonsny et al. does not specifically disclose the amines and amine oxides as claimed in the instant invention. However, Fonsny et al. broadly discloses C₈-C₁₈ alkyl amines and C₁₀-C₁₈ alkyl amine oxides useful as disinfectants which renders the amines and amine oxides claimed in the instant application obvious (see column 8 lines 45-67 and column 9 lines 14-59).

Fonsny et al. does not disclose the exact ranges of each of the components claimed in the instant application. However Fonsny et al. discloses ranges of each of the components claimed in the instant application that overlap with the ranges claimed in the instant application.

Fonsny et al. does not specifically disclose the inclusion of glycerol in the disinfectant composition.

Fonsny et al. discloses the use of 0.1% to 20% of a nonionic surfactant and/or an ethoxylated glycerol type compound (see column 2 lines 49-50).

Rasmussen et al. discloses in paragraph [0075] that glycerol is a nonionic surfactant.

Accordingly, one of ordinary skill in the art at the time of the instant invention would have found it obvious to combine the teachings of Fonsny et al., which teaches the use of 0.1% to 20% of a nonionic surfactant in a disinfectant composition with the teachings of Rasmussen et al. which discloses that glycerol is a nonionic surfactant.

Thus, since the composition of Fonsny calls for the inclusion of a nonionic surfactant, and glycerol is a known nonionic surfactant (as disclosed by Rasmussen et al.) one of ordinary skill in the art would be motivated to include glycerol in the composition disclosed by Fonsny with a reasonable expectation of similar success in providing a disinfectant composition.

Regarding claim 16, it would be obvious to an ordinary skilled artisan that any composition that contains detergent surfactants such as those disclosed in the compositions of Fonsny et al. would lyse bacteria. Thus claim 16 is also rendered obvious by Fonsny et al.

In conclusion claims 10-16 and 17-29 of the instant application are rendered obvious by Fonsny et al. in view of Rasmussen et al. since Fonsny et al. discloses disinfectant compositions comprising amines or amine oxides, in combination with detergents and Rasmussen et al. obviate the inclusion of glycerol in the composition.

Claims 18-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michaels, U.S. Patent No. 5,389,676.

Claims 18-20 of the instant application claim a method of inactivating a viral or microbial agent in a biological source material, comprising contacting the biological source material with a solution consisting essentially of an effective amount of an amine oxide, wherein the amine oxide is selected from the group consisting of: dimethyldecylamineoxide, dimethylundecylamineoxide, dimethyldidecylamineoxide and dimethyltridecylamineoxide. Claims 21-24 of the instant application claim the method of

claims 18-20 wherein the solution consists essentially of a detergent and an amine oxide. Claims 25-29 of the instant application also claim the method of claims 18-20 wherein the solution consists essentially of a polyol and an amine oxide.

Michaels teaches, in column 2 lines 20-45 compositions comprising surfactants including amine oxides with increased viscosity for use in the formulation of disinfectants. The compositions can be used in the treatment of mammalian tissue or cells with less irritation than the usual surfactants used for cleaning and disinfecting. Michaels further teaches that the surfactants useful as disinfectants and can be used in the treatment of damaged skin. Michaels discloses in column 3 line 63 through column 4 line 3 examples of amine oxides including decyl-N,N-dimethylamine oxide (equivalent to the dimethyldecylamineoxide).

Michaels teaches in column 5 lines 38-57 that preferred compositions contain 0.1-10% of the active ingredient one of which is the amine oxide. In addition to amine oxide, Michaels also discloses the presence of betaine detergents in the anti-infective or disinfectant solution (see column 3 lines 24-62). The betaine detergent is also present in an amount from 0.1-10% (see column 5 lines 38-57). Michaels further teaches, in col. 10 lines 20-60, zone of inhibition tests against bacteria *S. sanguis* M5 performed using a composition comprising 0.5% of C31G (a 1:1 betaine to amine oxide composition), and 5% glycerin (equivalent to glycerol).

Michaels does not specifically disclose a composition comprising one of the amine oxides claimed in claims 18-29 of the instant application.

However, Michaels does disclose that decyl-N,N-dimethylamine oxide (equivalent to the dimethyldecylamineoxide) is an example of an amine oxide useful in the anti-infective or disinfectant composition. Michaels discloses numerous amine oxides useful in the anti-infective or disinfectant composition. As such, an ordinary skilled artisan would be motivated to use any of the amine oxides listed in Michaels (see column 3 line 63- column 4 lines 3) with a reasonable expectation of similar success. As such claims 18-29 are rendered obvious in view of the teachings of Michaels.

Conclusions

Claims 10-14 and 16-29 are rejected. Claims 1-9 and 15 are cancelled. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA R. MCMILLIAN whose telephone number is (571)270-5236. The examiner can normally be reached on Monday-Thursday from 8:30 am- 6:00 pm and every other Friday from 8:30 am- 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kara R. McMillian/
Examiner, Art Unit 1617

KRM

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/SREENI PADMANABHAN/

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